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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,893	03/23/2005	Tatsuo Hoshino	K21418USWO C038435/018566	8833
7590 Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104			EXAMINER LILLING, HERBERT J	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 06/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,893

Applicant(s)

HOSHINO ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date March 23, 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1657

1. Receipt is acknowledged of the preliminary amendment, priority papers and a prior art information disclosure statement filed March 23, 2005.

2. Claims 1-10 are present in this application, which is a 371 of PCT/EP03/10494, which claims priority to EP 02021597.6 filed September 27, 2003.

3. It is noted that claims 3 and 7 are enabling and have not been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement with respect to the specific microorganism which has been deposited in more than one depository as noted by the following statement from U.S. Patent 6,242,233 which states that the strain has been deposited and is available from more than one depository:

A preferred strain is *Gluconobacter oxydans*. The strain most preferably used in the present invention is *Gluconobacter oxydans* DSM 4025, which was deposited at the Deutsche Sammlung von Mikroorganismen in Gottingen (Germany), based on the stipulations of the Budapest Treaty, under DSM No. 4025 on Mar. 17, 1987. The depositor was The Oriental Scientific Instruments Import and Export Corporation for Institute of Microbiology, Academia Sinica, 52 San-Li-He Rd., Beijing, Peoples Republic of China. The effective depositor was said Institute, of which the full address is The Institute of Microbiology, Academy of Sciences of China, Haidian, Zhongguancun, Beijing 100080, People's Republic of China.

Moreover, a subculture of the strain has also been deposited at the National Institute of Bioscience and Human-Technology, Agency of Industrial Science and Technology, Japan, also based on the stipulations of the Budapest Treaty, under the deposit No. *Gluconobacter oxydans* DSM No. 4025 (FERM BP-3812) on Mar. 30, 1992. The depositor was the Nippon Roche Research Center, 200 Kajiwara Aza Sotokochi, Kamakura-shi, Kanagawa-ken 247, Japan. This subculture is also most preferably used in the present invention.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1657

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific examples, does not reasonably provide enablement for the claims based on the prior art U.S. Publication 20010026933 published October 04, 2001 which Application is a division-of US application 09/203628, filed December 1, 1998, US Patent No. 6242233. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims since the reference as noted by the following cultures the same microorganism in the presence of substrate(s) within the scope of the claimed subject matter with the same pH, time and temperature but does not produce and recover Vitamin C:

Detail Description Paragraph:

[0081] *Gluconobacter oxydans* DSM 4025 (FERM BP-3812) was grown on an agar plate containing 5.0% D-mannitol, 0.25% $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$, 1.75% corn steep liquor, 5.0% baker's yeast, 0.5% urea, 0.5% CaCO_3 and 2.0% agar at 27.degree. C. for 4 days. One loopful of the cells was inoculated into 50 ml of a seed culture medium containing 2% L-sorbose, 0.2% yeast extract, 0.05% glycerol, 0.25% $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$, 1.75% corn steep liquor, 0.5% urea and 1.5% CaCO_3 in a 500 ml Erlenmeyer flask, and cultivated at 30.degree. C. with 180 rpm for one day on a rotary shaker. 10 ml samples of this culture were transferred into 500 ml Erlenmeyer flasks containing 100 ml of the same seed culture medium and cultivated in the same manner as described above. The seed culture thus prepared was used for inoculating 15 liters of medium, which contained 8.0% L-sorbose, 0.05% glycerol, 0.25% $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$, 3.0% corn steep liquor, 0.4% yeast extract and 0.15% antifoam, in 30 l jar fermentor. The fermentation parameters were 800 rpm for the agitation speed and 0.5 vvm (volume of air/volume of

Art Unit: 1657

medium/minute) for aeration at a temperature of 30.degree. C. The pH was maintained at 7.0 with sodium hydroxide during the fermentation. After 48 hours of cultivation, 30 liters of the cultivated broth containing the cells of *Gluconobacter oxydans* DSM No. 4025 (FERM BP-3812) by using the two sets of fermentors were harvested by continuous centrifugation. The pellets containing the cells were recovered and suspended in an appropriate volume of saline. After the suspension had been centrifuged at 2,500 rpm (1,000.times.g), the supernatant containing the slightly reddish cells was recovered to remove the insoluble materials derived from corn steep liquor and yeast extract which were ingredients in the medium. The supernatant was then centrifuged at 8,000 rpm (10,000.times.g) to obtain the cell pellet. As a result, 123 g of the wet weight of cells of *Gluconobacter oxydans* DSM No. 4025 (FERM BP-3812) were obtained from 30 liters of broth.

Detail Description Paragraph:

[0083] The cell paste (55 g) was suspended with 100 ml of the buffer and passed through a French pressure cell press. After centrifugation to remove intact cells, the supernatant was designated as the cell-free extract, and the cell-free extract was centrifuged at 100,000.times.g for 90 minutes. The resultant supernatant (165 ml) was designated as the soluble fraction of *Gluconobacter oxydans* DSM No. 4025 (FERM BP-3812). After this fraction had been dialyzed against the buffer, 126 ml of the dialyzed fraction having the specific activity on L-sorbose of 2.26 units/mg protein were used for the next purification step.

Detail Description Paragraph:

[0098] The reaction mixture containing the purified enzyme (1.56 mg), L-sorbose (0.142 mg), PMS (0.008 mg) and PQQ (0.3 mg) in 40 ml of the buffer was incubated for 1.5 hours at 30.degree. C. The reaction product was analyzed on thin layer chromatography and HPLC. As a result, the reaction product was identified as 2-KGA in comparison with an authentic sample of 2-KGA.

Applicant is required to insert the conditions which produces the Vitamin C directly from the reaction mixture.

Art Unit: 1657


4. **No claim is allowed.**

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
May 31, 2007



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